OCT - 6 2000

K001519

Summary of Safety and Effectiveness

1. Trade (Proprietary) Name

Acticoat™ 7 Dressing

2. Common/Classification Name

5-Layer AB Dressing/Wound or Burn Dressing

3. Applicant's Name & Address

Westaim Biomedical, Inc.
One Hampton Road
Exeter, NH 03833

4. Device Classification & Panel

A final classification for wound/burn dressings has not been implemented; Class II has been proposed by the General & Plastic Surgery Devices Panel.

5. Predicate Devices

Acticoat™ Antimicrobial Barrier Dressing (K955453)
Acticoat™ Foam Dressing (K000051)

6. Performance Standards

No applicable standards have been established under Sec. 514 of the FD&C Act.

7. Intended Use and Device Description

The Acticoat™ 7 Dressing is indicated for use partial and full thickness wounds, including decubitus ulcers, venous stasis ulcers, diabetic ulcers, first and second degree burns, grafts and donor sites. The dressing may be used over debrided and grafted wounds.

The antimicrobial dressing consists of 3-layers of silver-coated HDPE alternating with two inner layers of absorbent rayon/polyester. The dressing can be cut to size and maintains its antimicrobial activity for at least 7-days as shown *in vitro* against *Pseudomonas Aeruginosa* and *Staphylococcus Aureus*.

8. Biocompatibility

The biocompatibility of Acticoat™ 7 Dressing has been demonstrated through appropriate *in vivo* and *in vitro* tests as well as previous tests on individual components.

9. Summary of Substantial Equivalence[1]

The labeled indications and directions for use of the Acticoat™ 7 Dressing are equivalent to those of the predicate devices. The design, materials, and manufacturing methods of the Acticoat™ 7 Dressing are similar to those of the predicate Acticoat™ Dressings and do not raise any new issues of safety and effectiveness.

[1] Any statement made in conjunction with this submission regarding substantial equivalence to any other product only relates to whether the product can be lawfully marketed without premarket approval or classification and is not to be interpreted as an admission or used as evidence in patent infringement litigation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 6 2000

Mr. Steve Chartier
Manager, Regulatory and Clinical Affairs
Westaim Biomedical, Inc.
One Hampton Road
Exeter, New Hampshire 03833

Re: K001519
Trade Name: Acticoat™ 7 Dressing
Regulatory Class: Classified
Product Code: KMF
Dated: September 12, 2000
Received: September 12, 2000

Dear Mr. Chartier:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Milhorn

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Acticoat™ 7 Dressing

K001519

510(k) Number: K001519

Device Name: Acticoat™ 7 Dressing

Indications for Use:

The Acticoat™ 7 Dressing is indicated for use in partial and full thickness wounds including decubitus ulcers, venous stasis ulcers, diabetic ulcers, first and second degree burns, grafts and donor sites. The dressing may be used over debrided and grafted wounds.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription
(Per 21 CFR 801.109)

or

Over the Counter Use
(Optional Format 1-2-96)

Mark N. Melkerson

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001519